

Doc Case: AP.PRE.REQ

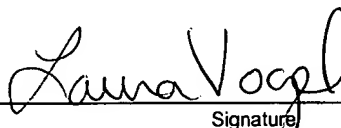
PTO/SB/33 (07-05)

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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
		1327.0440006/ELE/LAV	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____ Signature _____ Typed or printed name _____	Application Number	Filed	
	08/479,038	June 7, 1995	
	First Named Inventor		
	William N. DROHAN		
	Art Unit	Examiner	
	1631	Marschel, Ardin H.	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input type="checkbox"/> attorney or agent of record. Registration number _____</p> <p><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 <u>55,702</u></p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below".</p>			
<p><input checked="" type="checkbox"/> *Total of <u>1 (one)</u> forms are submitted.</p>			

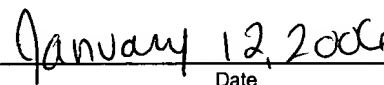

Signature

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Telephone number


Date

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UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

DROHAN *et al.*

Appl. No.: 08/479,038

Filed: June 7, 1995

For: **Supplemented Fibrin Matrix Delivery Systems** (*as amended*)

Confirmation No.: 7774

Art Unit: 1631

Examiner: Marschel, Ardin H.

Atty. Docket: 1327.0440006/ELE/LAV

Arguments to Accompany the Pre-Appeal Brief Request for Review

Mail Stop AF

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby submit the following Arguments, in five (5) or less total pages, as attachment to the Pre-Appeal Brief Request for Review (Form PTO/SB/33). A Notice of Appeal is concurrently filed.

Arguments

Applicants' arguments in the Reply under 37. C.F.R. §1.111 filed in response to the Office Action mailed on July 2, 2004, were not properly responded to by Examiner Marschel in the Final Office Action of July 13, 2005.

A. Rejections under 35 U.S.C. § 112, first paragraph

Claims 12, 13, 17-20, 24-32 and 34-38 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants traverse this rejection.

1) The Examiner's Final Office Action regarding Claims 17, 18, 25, 29-32 and 35-38 has failed to respond to all of Applicants' arguments in the March 2, 2005 Amendment and Reply

Independent claims 12, 34 and 36 each recite a supplement delivery system comprising a supplement and a tissue sealant that forms a fibrin matrix...wherein "said amount of said supplement is greater than the amount which is soluble in said fibrin matrix." Examiner Marschel alleged in the Final Office Action of July 13, 2005, that

Applicants point to page 22, lines 4-16, for support. Consideration of said page 22 citation reveals that only the inclusion of compounds such as TET etc. confers extended longevity which can be exploited to increase duration of a drug's release. This fails to provide written basis for any solubility or insolubility practice whatsoever, nor such solubility or insolubility in a fibrin matrix. This argument therefore is non-persuasive as clearly not providing written basis for the above new matter phrase. Applicants go on to point to page 104, lines 27-29, for written basis. Consideration of said page 104 citation reveals that lower solubility of antibiotics results in release over longer periods of time than highly soluble preparations. No written basis is present therein for solubility greater than in a fibrin matrix which is a requirement of the above cited new matter phrase and thus is also non-persuasive.

(July 13, 2005 Office Action, pages 2-3).

Upon receipt of the July 13, 2005 Final Office Action, Applicants telephoned Examiner Marschel and requested that he reconsider the Amendment and Reply filed on March 2, 2005, because he failed to respond to all of the arguments and evidence submitted by Applicants. (*See* September 12, 2005 Office Communication, pages 2-3). On September 12, 2005, Examiner Marschel mailed an Office Communication in which he reasserted the rejections of the July 13, 2005 Final Office Action, but again failed to respond to all of the support pointed to by Applicants in the March 2, 2005 Amendment and Reply. (*See* September, 12, 2005 Office Communication).

As described in detail in the March 2, 2005 Amendment and Reply, Applicants have demonstrated possession of the claimed invention as of the March 12, 1993 priority filing date, through text, figures and examples. (*See* March 2, 2005 Amendment and Reply, pages 14-20). The arguments set forth in the March 2, 2005 Amendment and Reply are largely representative of the discussions that took place during the in-person interview on October 6, 2004, with Examiner Marschel regarding the new matter rejection. (*See* October 6, 2004 Office Communication (Interview Summary)). During that interview, Examiner Marschel suggested claim amendment language that "appears to overcome these rejections if formally submitted." (October 6, 2004 Office Communication (Interview Summary)). Subsequent to the in-person interview,

Applicants formally submitted an Amendment and Reply in which the claims were amended as suggested by Examiner Marschel. (*See* March 2, 2005 Amendment and Reply, pages 5-11). In the March 2, 2005 Amendment and Reply, Applicants also pointed to text, figures and examples in support of the language "said amount of said supplement is greater than the amount which is soluble in said tissue sealant." (*See* March 2, 2005 Amendment and Reply, pages 18-20).

The March 2, 2005 Amendment and Reply was accompanied by the declaration of Dr. Stanley Friedman, a person of ordinary skill in the art of tissue sealant formulation and use. (*See* Declaration of Stanley Friedman, Ph.D.). In his declaration, Dr. Friedman explained how the application demonstrates sustained release of a supplement from a tissue sealant when added above the solubility limit. Some of the specific support for sustained release of a supplemented tissue sealant, wherein the supplement is loaded above its solubility limit¹ in the specification of priority application USSN 08/479,038 includes Example 21 at pages 107-109; page 21, lines 8 to the end of page; page 22, lines 4-16; Figures: 12, 24, 25, 28, 31(a) and 32; page 104, lines 27-29. (*See* March 2, 2005 Amendment and Reply, pages 18-20).

Examiner Marschel has not responded to all of Applicants' arguments and evidence in support of the assertion that claims 12, 13, 17-20, 24-32 and 34-38 are fully supported by USSN 08/479,038, filed March 12, 1993. In the July 13, 2005 Final Office Action, Examiner Marschel commented on the text at pages 22 and 104 of the specification, but failed to respond to any of the other evidence provided by Applicants in response to the written description rejection, *i.e.*, Example 21 at pages 107-109; page 21, lines 8 to the end of page; Figures: 12, 24, 25, 28, 31(a) and 32; and the Friedman Declaration. (*See* March 2, 2005 Amendment and Reply, pages 18-20).

¹ As discussed during the interview of October 6, 2004, and the in the Declaration of Dr. Julia Lathrop, the solubility limit of a supplement in a medium such as tissue sealant may readily be determined by one of ordinary skill in the art. (*See* November 4, 2005 Amendment and Reply).

Examiner Marschel's response also indicates that the parts of the specification that he did comment on (pages 22 and 104 of the application) were not considered in their entirety, or in light of the specification as a whole because those comments ignored facts conveyed by the relevant text. Thus, Applicants reassert that consideration of the specification as a whole provides adequate written descriptive support of the claims under 35 U.S.C. § 112, first paragraph.

2) The Examiner has failed to properly accord priority to the March 12, 1993 filing date in the presently pending application

The presently pending application claims priority under 35 U.S.C. § 120 to USSN 08/031,164 ("the '164 application"), now abandoned, filed March 12, 1993. As a consequence of Examiner Marschel's rejection under 35 U.S.C. § 112(1), discussed above, he has not accorded the presently pending application the benefit of priority to the March 12, 1993 filing date. As also discussed above, Applicants respectfully assert that the presently pending claims are fully supported by the '164 application as-filed, and therefore should be accorded priority back to March 12, 1993.

B. Rejections under 35 U.S.C. § 103(a)

Claims 17, 18, 25, 29-32 and 35-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,607,694 ("Marx"); taken in view of U.S. Patent No. 4,708,861 ("Popescu"). Applicants traverse this rejection.

1) The Examiner's Final Office Action has failed to present a *prima facie* case of obviousness for claims 17, 18, 25, 29-32 and 35-38

Examiner Marschel has failed to present a *prima facie* case of obviousness for the presently pending claims because one of the two cited references, Marx, is not prior art to the presently pending application under 35 U.S.C. § 102(b), and the Popescu reference alone does not

disclose or suggest all the limitations of the rejected claims. As discussed above, the presently pending application claims priority back to March 12, 1993, the filing date of the '164 priority application. The earliest filing date to which the Marx patent claims priority is February 17, 1994, which is almost a year after the effective filing date of the presently pending application. Thus, the Marx reference is not prior art under 35 U.S.C. § 102(b) to the presently pending application. As discussed in Applicants' March 2, 2005 and November 4, 2005 Replies, the remaining reference, Popescu does not disclose or suggest all the limitations of any of claims 17, 18, 25, 29-32 or 35-38. (See March 2, 2005 Amendment and Reply, pages 22-24; *see also* November 4, 2005 Amendment and Reply, pages 14-15). Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Conclusion

Applicants respectfully assert that claims 12, 13, 17-20, 24-32 and 34-38 are in condition for allowance for the reasons stated above. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Date: January 12, 2006

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